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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,832	06/03/2002	Paul Zev Zimmet	229752000701	3004

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,832	ZIMMET ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 9-19* is/are pending in the application.

4a) Of the above claim(s) *11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/22/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 9/14/06. Claims 7, 9 and 10 have been amended. Claim 8 is canceled. Claims 11-19 are withdrawn. Therefore, claims 7, 9 and 10 are currently pending and are examined.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112, first paragraph, maintained

4. The rejection of claims 7, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. The basis for this rejection is set forth for claims 7, 9, and 10 in the previous Office Actions dated 14 April 2006 at pages 5-7 and below. Applicant's arguments filed 16 September 2006, as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Although, SEQ ID NO: 14 (part of SEQ ID NO: 2) and SEQ ID NO: 13 are disclosed in the specification, amino acid sequence having at least 90% similarity to all or part of SEQ ID NO: 14 are not disclosed. Similarly protein encoded by nucleotide sequence having at least 90% similarity to all or part of SEQ ID NO: 13 and/or is capable of hybridizing to SEQ ID NO: 13 under high stringency conditions are also not

disclosed in the specification. In addition, there is no disclosure for agonist and antagonist. Since no structure or activity is disclosed there is no way of ascertaining if a compound is an agonist or an antagonist.

Applicant asserts that the disclosure more than adequately meets the burden of the "Written Description Requirement" of the Office. It is asserted that the presently claimed invention is directed to the Applicants discovery that SEQ ID NO: 14 is produced in larger amounts in the hypothalamus tissue of the obese animals compared to lean animals. Although, the Applicant has conducted some experiments using the shorter polypeptide of SEQ ID NO: 14 (see example 17), the higher expression in hypothalamus appears to be limited the beacon gene of 169 bp (see example 12 of the specification).

The broad-brush discussion of making and screening for variants in the instant specification does not constitute a disclosure of a representative number of members. No such variants were made or shown to have activity. Only the polypeptide of SEQ ID NO: 2 or 14 is disclosed with no disclosed function. The overexpression of the protein in hypothalamus tissue of the obese animals compared to lean animals is not a function. Furthermore, similarity implies that the sequence only resembles a given sequence and is not identical. The specification's general discussion of making and screening for variants constitutes an invitation to experiment by trial and error. Such does not constitute an adequate written description for the claimed variants. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. To provide evidence of possession of a claimed genus, the specification must provide

sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims are a partial structure in the form of a recitation of percent identity and a requirement that the polypeptide is overexpressed in hypothalamus tissue of obese animals compared to lean animals. There is no identification of any particular portion of the structure that must be conserved in order to conserve the required function or that the described function is truly representative of all members of the claimed genus. Clearly, such does not constitute disclosure of a representative number of examples of, nor adequate written description for, the claimed genus.

Furthermore, the specification and the claims do not disclose the identification of any particular portion of the beacon structure that must be conserved in order to conserve the required function. Therefore, the rejection of record is maintained.

5. The rejection of claims 7, 9 and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons set forth in the Office Action dated 14 April 2006 (pages 8-11) and below. Wand's factors were discussed in the previous Office Action dated 4/14/06.

The specification, while being enabling for SEQ ID NO: 14 (part of SEQ ID NO: 2) and SEQ ID NO: 13, amino acid sequence having at least 90% similarity to all or part of SEQ ID NO: 14 are not enabling. Similarly protein encoded by nucleotide sequence having at least 90% similarity to all or part of SEQ ID NO: 13 and/or is capable of hybridizing to SEQ ID NO: 13 under high stringency conditions are also not enabling. In addition, the specification does not provide enabling disclosure for agonist and antagonist.

Applicant asserts that claims as amended are enabled by the specification. It is asserted that the specification is replete with guidance as to how one of skill in the art would make modifications to the claimed protein. Applicant contends that one of skill in the art would consider the generation of modified proteins which demonstrate 90% similarity to SEQ ID NO: 14 using routine amino acid substituions/modification. Applicant has provided little or no guidance beyond the mere presentation of sequence data (SEQ ID NO: 2 or 14) to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions and yet maintain the function of the protein. Furthermore, similarity implies that the sequence only resembles a given sequence and is not identical. The overexpression of the protein in hypothalamus tissue of the obese animals compared to lean animals is not a function. Therefore, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its

full scope, because the skilled artisan would have no reasonable expectation of being able to make and use beacon variants.

In addition, the lack of direction/guidance presented in the specification regarding which variants of polynucleotides of SEQ ID NO: 13 encoded proteins would retain the desired activity, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, the absence of working examples directed to variants and the breath of claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. Applicant has not established a nexus between the degree of homology and any function. Until one identifies a particular variant that demonstrates a specific or not, one of skilled in the art would not know the expression profile of the variant. Modifications to polynucleotides encoding the protein, e.g., by substitutions or deletions, would often result in deleterious effects to overall activity and effectiveness of the protein. Furthermore, it is also well known in the art that hybridization under high stringency conditions would yield nucleic acid molecules that are structurally unrelated.

Applicant has also not provided any guidance with respect to the agonists and the antagonists. It is unclear what function is to be modulated by the agonists and the antagonists. Further the specification fails to provide enabling disclosure as to what compounds will be considered agonists and antagonists. Therefore, it would require undue experimentation for one skilled in the art to make and use the claimed agonists and the antagonists.

Accordingly, the disclosure fails to enable such a myriad of the claimed polypeptide molecules that not only vary substantially in length but also in amino acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of amino acid molecules. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of the molecules embraced by the instant claims. Therefore, the rejection of record is maintained.

Conclusion

6. No claims are allowable. However, claims drawn to protein of comprising SEQ IDNO: 14 and the protein encoded by SEQ ID NO: 13 are allowable over prior art.

7. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647
November 16, 2006

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud